

Hepatitis Testing at MDHHS

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Prevent Disease – Promote Wellness – Improve Quality of Life



Hepatitis Serology

- Hepatitis B Surface Antigen
 - Hepatitis B Surface Antibody
 - Hepatitis C Antibody
 - Hepatitis A IgM Antibody
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- Bio-Rad's Enzyme Immunoassay (EIA) performed on the EVOLIS instrument. Cut-off value is based on absorbance readings.



Hepatitis B Surface Antigen

- Bio-Rad's GS HBSAg EIA 3.0 kit
- This marker is the earliest indicator of acute infection
- A positive screen is performed in duplicate, then confirmatory testing is performed.
- Acceptable specimen: Minimum 1 ml serum shipped frozen, refrigerated or at room temperature
- TAT: 2-5 days

- **Possible results:**

- *HBsAg Absent:

The absence of detectable HBsAg rules out current hepatitis B infection however, false negative results may occur if the quantity of HBsAg is below the detectable limits of the assay or if the specimen is collected too early following exposure. The timing of specimen collection in conjunction with clinical signs and symptoms should be considered.

- *HBsAg Present:

The presence of HBsAg in this assay indicates the patient is actively infected with Hepatitis B virus however; recently vaccinated individuals may exhibit transient HBsAg reactivity for up to 18 days.

Hepatitis B Antibody

- Bio-Rad's Anti-HBs MONOLISA EIA Kit
- Acceptable specimen: Minimum 1 ml serum shipped frozen, refrigerated or at room temperature
- TAT: 2-5 days
- Absorbance value readings are compared to the mean absorbance of the 10 mIU/mL calibrators, which is calibrated against the World Health Organization (WHO) reference standard.

- **Possible results:**

*ABSENT-HBs antibody levels (anti-HBs) < 9 mIU/ml

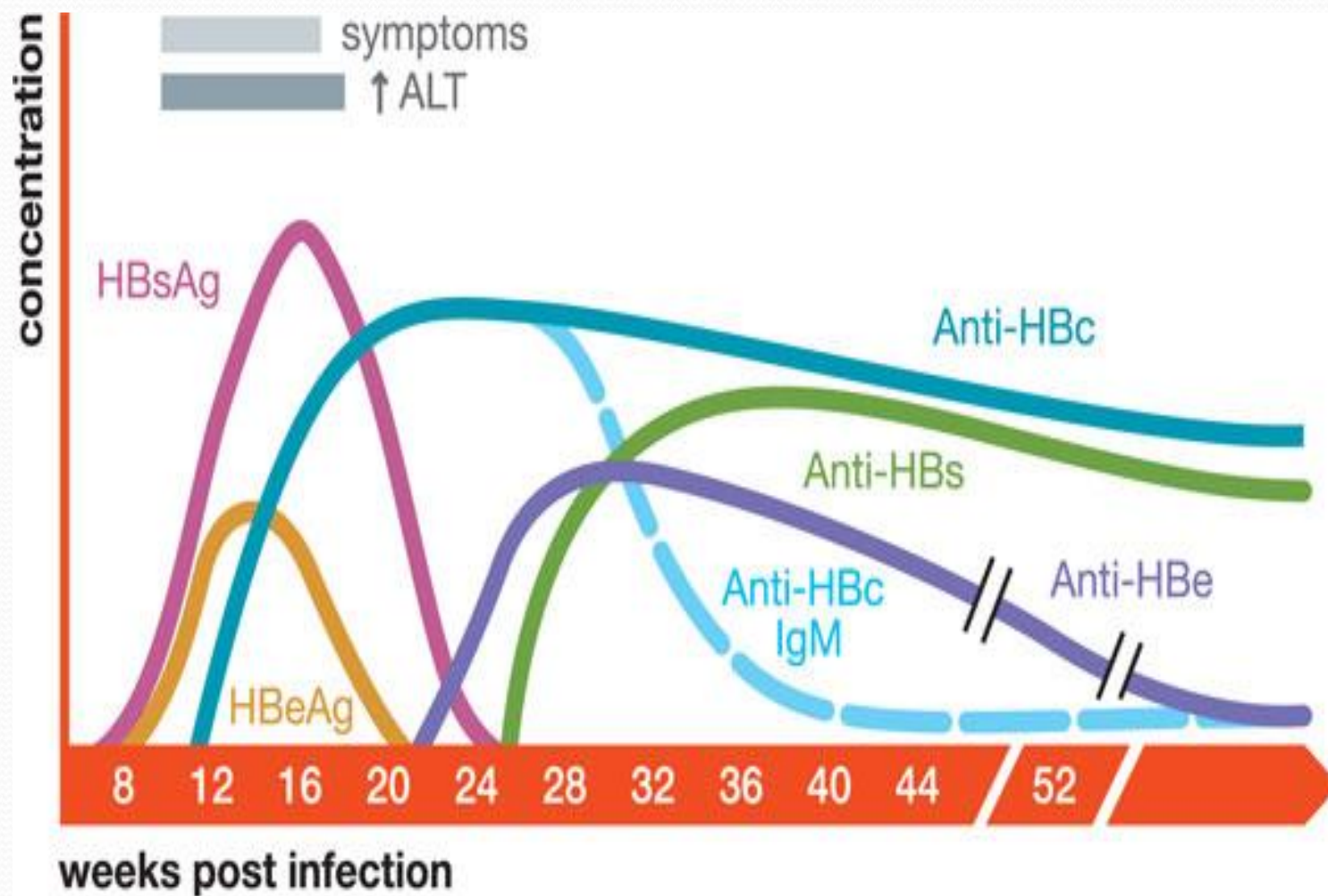
Result indicates no serologic evidence of previous exposure to HBV and the patient may lack immunity.

*PRESENT-HBs antibody levels (anti-HBs) >11 mIU/ml

Result indicates serologic evidence of previous exposure or vaccination to HBV. A positive test for anti-HBs can be a useful adjunct for assessing immunity to Hepatitis B virus post HBV infection (clinical recovery) or post vaccination.

*EQUIVOCAL-HBs antibody levels (anti-HBs) ≥ 9 but ≤ 11 mIU/ml

Request a second specimen for further testing.



Bio-Rad

Hepatitis C Antibody

- Ortho HCV 3.0 kit supplied by Bio-Rad
- Detects IgG antibodies
- Acceptable specimen: Minimum 1 ml serum shipped frozen or refrigerated.
Request shipping unit 8A and submit two tubes of serum (one for PCR if reactive).
- TAT: 2-5 days

- **Possible results:**

***NON-REACTIVE**

A nonreactive anti-HCV antibody result does not exclude the possibility of exposure to hepatitis C virus. Antibody levels below detectable limits may be due to early infection or weakened antibody response in immunocompromised patients. HCV antibody generally develops within 2-8 weeks following exposure however, in some individuals antibody may be undetectable for up to 6 months. If early infection is suspected or the patient is immunocompromised and there is clinical evidence of HCV disease, HCV RNA testing may be warranted. HCV RNA testing on HCV EIA non-reactive specimens is available only after consultation with the Virology Section Manager at 517-335-8099.

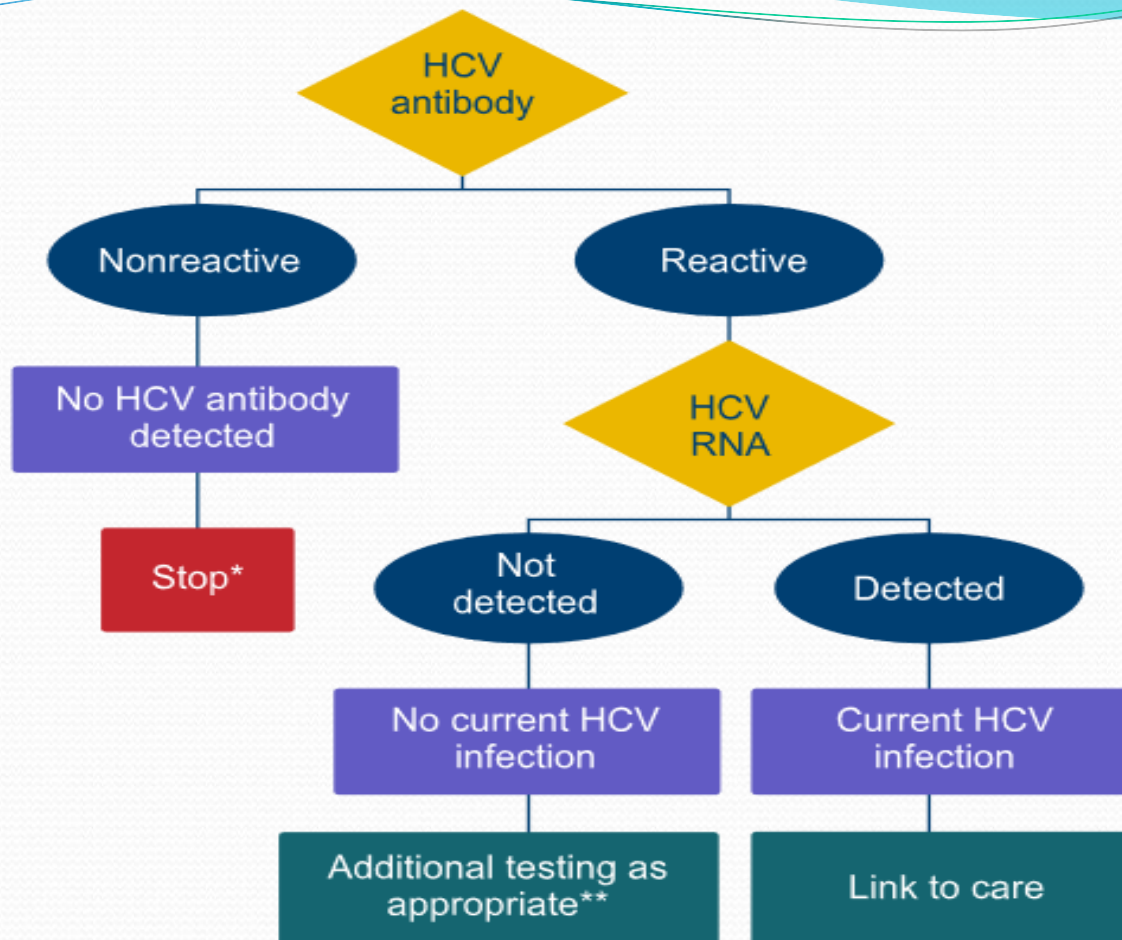
***REACTIVE**

A reactive HCV antibody result is consistent with current infection, previous infection, or biological false positive. If the serum specimen is received frozen or refrigerated, HCV RNA testing will be performed to identify current infection.

Kit 8A for HCV Submission

Note: Two Specimen Tubes

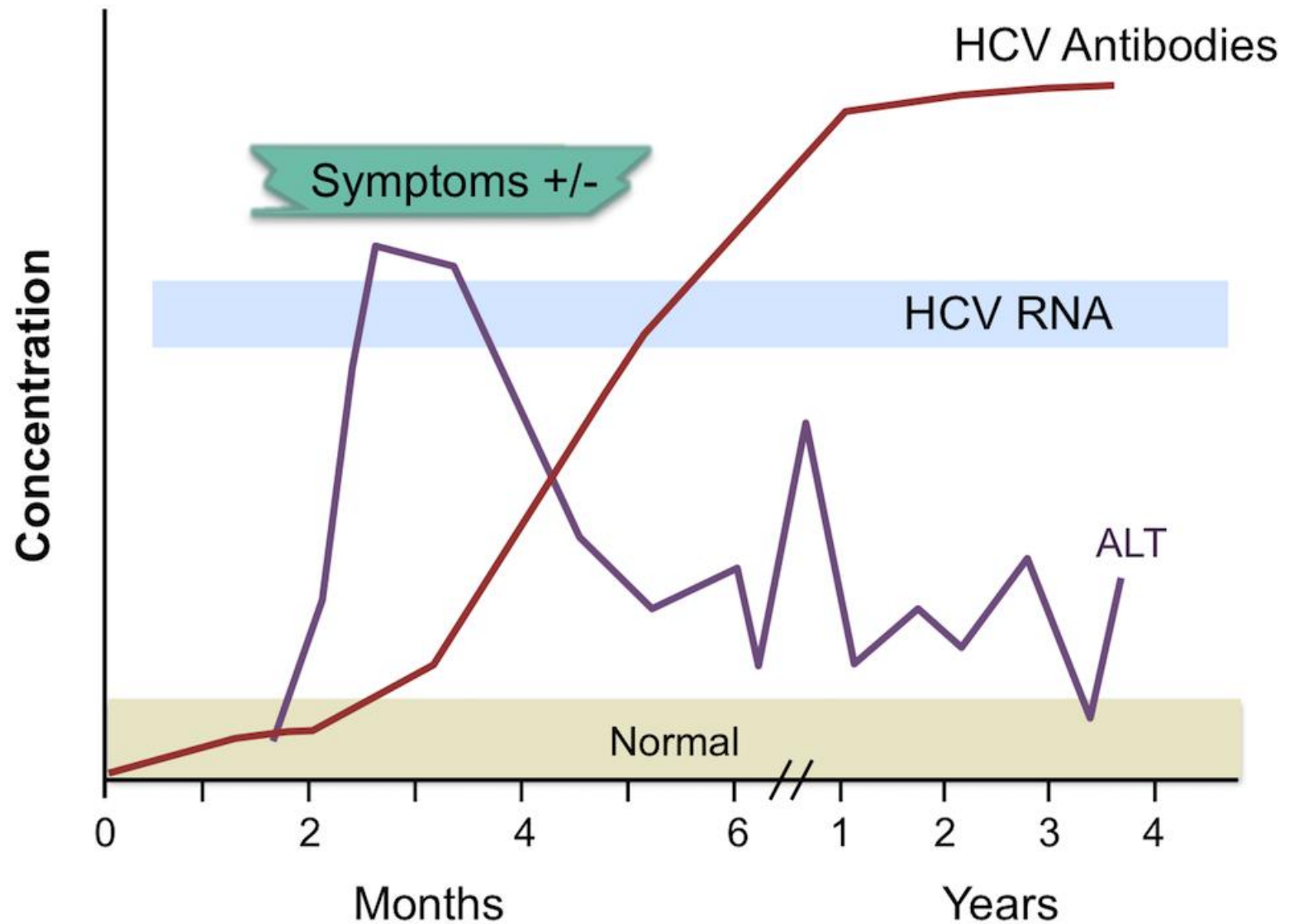




* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

** To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).



CDC

Time After Exposure

Hepatitis A Antibody

- MONOLISA Anti-HAV IgM Capture EIA Kit
- Acceptable specimen: Minimum 1 ml serum shipped frozen or refrigerated.
- TAT: 2-5 days
- Most clinical laboratories are performing this testing. MDHHS has asked submission of all positive IgM specimens for PCR/genotyping. These results are not yet reportable in our LIMS system.

- **Possible results:**

- *ABSENT

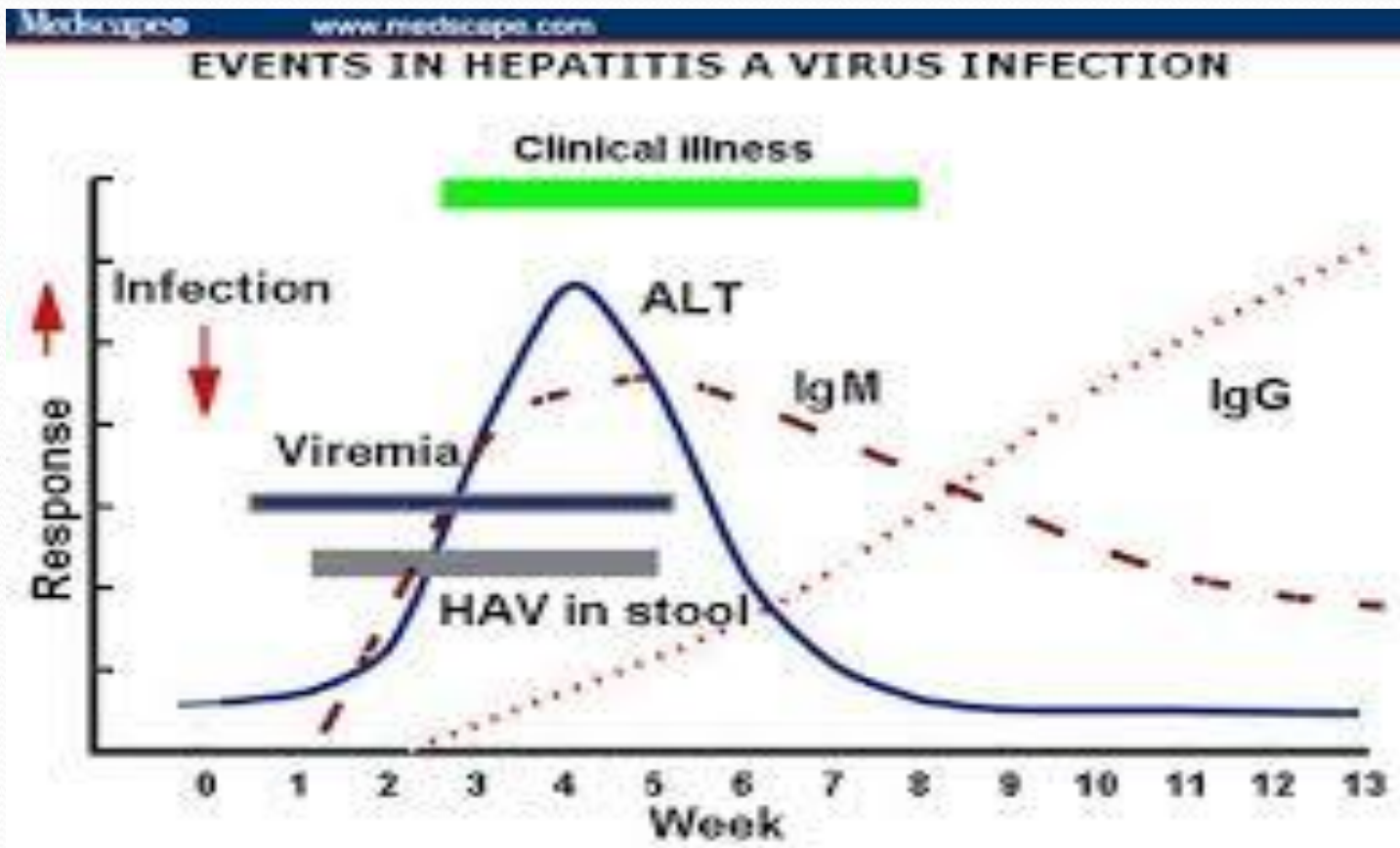
The absence of IgM antibody does not exclude the possibility of acute infection. Levels of HAV IgM antibody may be below the detection limits of the assay during early infection. The timing of specimen collection in conjunction with clinical symptoms should be considered.

- *PRESENT

The detection of Hepatitis A IgM antibody does not necessarily imply acute infection. Hepatitis A IgM antibody persists in some individuals more than one year following exposure.

- *EQUIVOCAL-Please submit a second specimen for further testing

Patients exhibiting equivocal results should be retested at approximately two week intervals. A change in result from equivocal to positive indicates acute infection whereas no change is normally associated with late or recovering disease or the presence of low level interfering substances.



Medscape

Accessing MDHHS Bureau of Laboratories Website

https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5103---,oo.html

Or michigan.gov/mdhhs ➡

Go to top left middle tab “MDHHS-Lab Services”

Or through Google:

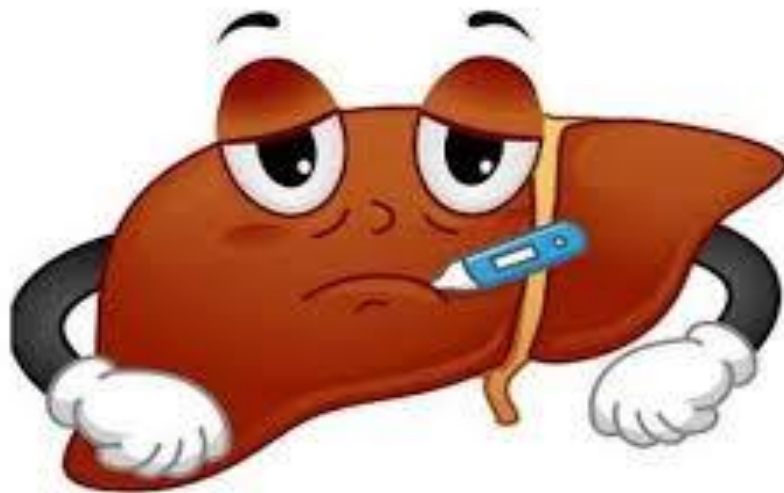
Type “MDHHS Lab” ➡

MDHHS-Lab Services-State of Michigan

To request specimen kits, call BOL shipping at 517-335-9040



Thank you!



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517-335-8100

Thehealthsite.com